DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Byrne Medical, Inc.
% Mr. Jay Y. Kogoma
Responsible Third Party Official
Intertek Testing Services NA, Inc.
2307 E. Aurora Road, Unit B7
Twinsburg, OH 44087

JUL 27 2015

Re: K093665
Trade/Device Name: Endo SmartCap™
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FAJ
Dated (Date on orig SE ltr): November 24, 2009
Received (Date on orig SE ltr): November 25, 2009

Dear Mr. Kogoma,

This letter corrects our substantially equivalent letter of December 15, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number K093665

Device Name: Endo SmartCap™

The Endo SmartCap™ is intended to be used with an air or CO2 source and/or a pump along with a sterile water source to supply air or CO2 and sterile water to an endoscope during endoscopic procedures.

Prescription Use **YES** (21 CFR 801 Subpart D) AND/OR Over-The-Counter Use **NO** (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K093665

Byrne Medical, Inc.
The Universal Irrigation Solution

3150 Pollok Dr.
Conroe, TX 77303
Main Line: (936) 539 - 0391
Main Fax: (936) 539 - 2381

DEC 15 2009

510(k) Summary

As Required by 21 CFR 807.92(c)

510(k) Number K093665

TABLE 1 – Company Information

Company	Byrne Medical Incorporated
Address	3150 Pollok Drive Conroe, TX 77303
Contact	Chris Hierholzer, Regulatory Affairs Manager
Phone	936-539-0391
Fax	936/539-2381
e-mail	chierholzer@byrnemedical.com

TABLE 2 – Device Information

Common Name	Sterile Water Bottle Adapter
Proprietary Name	Endo SmartCap™
Classification Name	Endoscopes and Accessories, KOG, 21 CFR §876.1500,

TABLE 3 – Predicate Devices

Device	Manufacturer	510(k) Number
MD-431 Water Bottle	Olympus Corp Center Valley, PA	K790071
Endo SmartCap™	Endo SmartCap™ Company Houston, TX	K971125